REMARKS

Claims 1 - 12 are currently pending. Claims 14 – 16 have been withdrawn. Claim 1 is the only pending independent claim. Claims 1, 2, 5, 10, and 12 have been rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Number 5,500,416 to Miyazawa et al. ("Miyazawa"). Claims 1 – 6 and 8 – 12 have been rejected under 35 U.S.C. § 102(e) as allegedly anticipated by WIPO Publication Number WO 2004/015124 to Menart et al. ("Menart '124"). Claims 1 – 12 have been rejected under 35 U.S.C. § 103(a) as allegedly obvious from Menart '124 combined with Vuillard et al., Biochemistry Journal 305: 337 – 343 (1995) ("Vuillard"). Certain of these claims are also said to be subject to a "provisional" obviousness-type double patenting rejection based on two pending applications (U.S. Application Serial Nos. 10/577,285 and 10/522,826).

Each of the foregoing rejections is respectfully traversed. Favorable reconsideration is requested in view of the above amendments and following remarks. No new matter has been added by any amendments made to the claims.

I. Claim 1 (and its dependants) Patentably Distinguishes Over Miyazawa

Independent claim 1 calls for, *inter alia*, a pharmaceutical composition which comprises an active pharmaceutical ingredient and a non-detergent sulfobetaine. The claimed "non-detergent sulfobetaine" is defined in the specification as sulfobetaine which does not form micelles in aqueous media. *See* specification at page 3.

Use of a non-detergent sulfobetaine is a key feature of Applicants' invention. Applicants attach selected pages from the reference, Bhairi, Srirama M., *A Guide to the Properties and Uses of Detergents in Biology and Biochemistry*, Calbioshem, 2001, which explain distinctions between surfactant and non-surfactant sulfobetaines.[1] Again, non-detergent sulfobetaines do not form micelles in water and, therefore, do not exhibit surfactant activity in aqueous media.

---

[1] The terms "surfactant" and "detergent" are broadly interchangeable as used in the present application. As explained in the Bhairi reference, the terms "detergent" and "surfactant" are also normally used interchangeably in the field of biochemistry. Among other things, detergents and surfactants both act to modify the surface tension of water and lead to the formation of micelles in water so as to increase the solubility of certain materials in water-based solutions/mixtures. *See* Bhairi, page 4. *See* Bhairi, pages 2, 19. This lack of micellar formation is believed to be attributable to the relatively short length of the hydrophobic tails of this class of sulfobetaines. *See* Bhairi, page 19.

Miyazawa fails to disclose or suggest the use of NDSBs as part of a composition containing an active pharmaceutical agent. The composition of Miyazawa is only said to contain sulfobetaines of a type which form micelles in water. These are surfactant or detergent sulfobetaines, not NDSBs.

Since Miyazawa fails to disclose the use of NDSBs in pharmaceutical compositions as called for in Claim 1, it is respectfully submitted that the anticipation rejection of Claim 1 based upon Miyazawa cannot stand and must be withdrawn.

Dependent Claims 2, 5, 10, and 12 depend from independent Claim 1, and therefore include all the limitations of Claim 1. Since Claim 1 is not anticipated by Miyazawa, these dependent claims also are not anticipated by Miyazawa by operation of law. Accordingly, withdrawal of the rejection of dependent Claims 2, 5, 10, and 12 and allowance of the same is also respectfully solicited.

II. The Effective Date of the § 102(e) Reference Has Been Overcome

Menart '124 was cited against Claims 1-6 and 8-12 under § 102(e) as an alleged anticipatory reference. Pursuant to M.P.E.P. § 201.15 and 37 C.F.R. § 1.55, Applicants provide herewith an English language translation of the parent application of the instant application as filed in Slovenia on December 23, 2003. The filing date of the parent Slovenian application predates the publication date of Menart '124, and Menart's publication date of February 19, 2004, does not predate the December 22, 2004, filing date of Applicants' PCT Application No. PCT/SI2004/000043 by more than one year. Applicants' claim to the priority of its Slovenian parent case is being made during the pendency of this application in order to predate and therefore overcome a reference cited by an examiner under § 103(e), as allowed under 37 C.F.R. § 1.55(3)(ii). A statement that the English translation of the certified copy is accurate accompanies the same as required under 37 C.F.R. § 1.55(4)(ii).

In view of the submission of this certified English translation of the Slovenian priority application, it is submitted that Menart '124 is no longer properly citable against the current claims. Accordingly, all rejections of claims 1-6 and 8-12 based on Menart '124 should be withdrawn.

III. The Rejections Under § 103(a) are no longer Viable

Without conceding or acquiescing in the Examiner's reasoning in support of her §103(a) rejections and while expressly reserving all rights and arguments to the contrary and or in opposition thereto, Applicants note that the alleged obviousness rejections are dependent on the availability of Menart '124 as a citable reference under § 102. Since Menart '124 is not citable against Applicants' claims, all obviousness rejections based thereon must also be withdrawn.[2]

The secondary reference Vuillard plainly does not alone disclose or suggest any of Applicants' claims. Therefore, with the withdrawal of Menart '124, all rejections under § 103 are no longer viable, and should be withdrawn.

IV. The Provisional Obviousness-Type Double Patenting Rejections Are Not Well Taken.

Both applications cited by the Examiner in the alleged obviousness-type double patenting rejections in paragraphs 11 and 12 are owned by the same entity, Lek Pharmaceuticals d.d., or are under an obligation to assign to the same entity, Lek Pharmaceuticals d.d. It is believed the '285 and '286 applications are relied on by the Examiner under at least one of the §§ 102(e), (f), or (g), and that the Examiner at least implicitly alleges that certain claims are "obvious" variants of certain other claims. The Examiner is therefore necessarily invoking § 103 in support of her obviousness-type double patenting rejections since § 103 is the only part of the Patent Act which purports to deal with matters of "obviousness." By operation of § 103(c), the '285 and '286 applications are not properly citable against the claims of the present application, as discussed above with regard to Menart '124.[3] (See attached copy of assignment executed by all named inventors in the present case in favor of Lek Pharmaceuticals d.d.).

If the Examiner believes Applicants are incorrect about the application of § 103(c) to this part of the Office Action (the obviousness-type double patenting rejections), and provides a convincing line of argument as to why § 103(c) does not preclude the Examiner's reliance on the

[2] This includes, but is not limited to, the citability of Menart '124 (or the lack thereof) considered from the perspective of Section 103(c). Since Menart '124 is cited against the subject claims only under 35 U.S.C. § 102(e) and both the current application and Menart '124 are assigned or are subject to an obligation to assign to the same entity (Lek Pharmaceuticals d.d.), it is apparent from the plain language of § 103(c) that the teachings of Menart '124 cannot serve as a lawful basis to render the subject claims unpatentable.

[3] In point of fact, Menart '124 is also disqualified from being applied against Applicants' claims under § 103 by application of §103(c) for the very same reason. Lek Pharmaceuticals d.d. owns both Menart '124 and the present case.

'285 and '286 applications, Applicants will consider filing Terminal Disclaimers in order to obviate and overcome citation of these applications as soon as they issue as patents. [4]

In view of the foregoing, Applicants respectfully request the Examiner reconsider the application, withdraw all rejections and objections and issue a Notice of Allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our Deposit Account No. 12-2355.

Respectfully submitted,

LUEDEKA, NEELY & GRAHAM, P.C.

By: /Mark S. Graham/

Mark S. Graham
Registration No. 32,355

MSG:lal
Enclosures:

1. Assignment
2. English Language Translation of Slovenian Priority Application

Date: January 21, 2009
P.O. Box 1871
Knoxville, Tennessee 37901
(865) 546-4305

[4] This also assumes the '285 and '286 applications issue as patents with a priority date earlier than the priority date to which the present application is entitled. And this is also without waiver of Applicants' right to argue that one or more claims of the subject '285 and/or '286 applications and one or more claims of the current application, as currently drafted or as ultimately allowed, are not in fact "obvious variants" of one another for purposes of correct application of the doctrine of obviousness-type double patenting.